

Minimally Invasive Breast Fibroadenoma Excision Using an Ultrasound-Guided Vacuum-Assisted Biopsy Device

Minimalinvasive operative Entfernung von Fibroadenomen der Brust mittels der sonografisch geführten Vakuumsaugbiopsie

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Key words

ultrasound-guided vacuum aspiration biopsy, fibroadenoma of the breast

Schlüsselwörter

ultraschallgesteuerte Vakuumsaugbiopsie, Fibroadenom der Brust

received 6.9.2016

revised 5.1.2017


accepted 5.1.2017

Bibliography

DOI <http://dx.doi.org/10.1055/s-0043-100387>
Geburtsh Frauenheilk 2017; 77: 176–181 © Georg Thieme Verlag KG
Stuttgart · New York | ISSN 0016-5751

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 Deutsche Version unter:
<http://dx.doi.org/10.1055/s-0043-100387>

ABSTRACT

Introduction We studied the extent to which an ultrasound-guided vacuum-assisted biopsy device (“hand-held Mammotome”) could be used not only as a valuable tool for investigation of suspicious breast lesions, but also therapeutically for the complete removal of breast fibroadenomas.

Materials and Methods 132 aspiration biopsies showing fibroadenoma on histology were collected retrospectively. We ascertained whether there were residual findings on breast ultrasound at a median follow-up of approx. 9 months following biopsy. A questionnaire was used to determine the complication rate, patient satisfaction and acceptance of the procedure.

Results In this study complete fibroadenectomy was achieved at aspiration biopsy in 76% of cases (n = 132). Compared to fibroadenomas larger than 2.51 cm³ (59%), those smaller than 2.5 cm³ were completely removed more often (87.6%; p < 0.05). The procedure is associated with very little pain during and after biopsy and minimal haematoma development, both factors supporting a high rate of acceptance among patients.

Conclusion Ultrasound-guided vacuum-assisted biopsy is safe and associated with very few complications. Its additional therapeutic potential is dependant on the size of the benign lesion as measured at initial ultrasound.

ZUSAMMENFASSUNG

Einleitung Im Folgenden wurde untersucht, inwiefern die Vakuumsaugbiopsie unter sonografischer Sicht („hand-held Mammotome“), nicht nur ein wertvolles Mittel zur Abklärung suspekter Befunde in der Brust darstellt, sondern auch therapeutisch zur Kompletterentfernung von Fibroadenomen in der Brust eingesetzt werden kann.

Material und Methoden 132 Vakuumsaugbiopsien, deren Histologie ein Fibroadenom ergab, wurden durch eine retrospektive Auswertung erfasst. Es wurde untersucht, ob in einem medianen Nachbeobachtungszeitraum von etwa 9 Monaten ein sonografischer Restbefund nachzuweisen war. Komplikationsrate, Patientenzufriedenheit und Akzeptanz des Eingriffs wurden mittels Fragebogen analysiert.

Ergebnisse In der vorliegenden Arbeit konnten mittels Vakuumsaugbiopsie der Brust in 76% der Fälle (n = 132) Fibroadenome komplett entfernt werden. Fibroadenome kleiner als 2,5 cm³ konnten im Vergleich zu Befunden größer als 2,51 cm³ zu 87,6% vollständig entfernt werden (p < 0,05). Die schwache Schmerzintensität während und nach der Biopsie wie auch die geringfügige Hämatomausbildung unterstreichen die hohe Akzeptanz der Methode bei den Patientinnen.

Zusammenfassung Die ultraschallgesteuerte Vakuumsaugbiopsie ist eine sichere, komplikationsarme Biopsiemethode. Das zusätzliche therapeutische Potenzial der Technik ist abhängig von der initialen sonografischen Größe der benignen Befunde.

Introduction

Fibroadenomas are the most common tumours of the female breast [1]. They originate from epithelial mesenchyme and mostly occur as solitary nodules. These tumours are cell-rich and contain both stroma cells and epithelial components. They manifest macroscopically as well defined, rubbery tumours with a shiny whitish, lobulated cut surface [2]. They normally grow to around 1–2 cm and are commonly first detected on palpation. In many instances, however, clinically asymptomatic fibroadenomas are detected as incidental findings by modern imaging techniques in the context of breast cancer screening [3]. Typical ultrasound findings will suggest the diagnosis, which is then confirmed on histology using high speed punch biopsy [4].

Cyclical pain, lesions experienced by patients as aesthetically unpleasing and pronounced carcinophobia are some of the possible indications for removal of fibroadenomas [4] and this is classically performed by excision biopsy. However, excision biopsy requires anaesthesia. It also causes scarring of both the skin and breast tissue that in these mostly young patients is not only cosmetically unpleasing, but can also lead to differential diagnostic problems at future breast imaging. A minimally invasive excision technique would therefore be beneficial [5].

The ultrasound-guided vacuum-assisted aspiration biopsy (“hand-held Mammotome” HHM) has become a valuable tool for minimally invasive investigation of suspicious breast lesions. In contrast to surgical excision it can be performed under local anaesthesia and leaves neither cosmetic impairment nor problematic breast tissue scars [6, 8, 15, 23].

This study investigated the therapeutic use of ultrasound-guided vacuum-assisted biopsy for the removal of breast fibroadenomas. In addition, complication rates and patient satisfaction were analysed.

Materials and Methods

Over a period of 7 years 132 patients underwent an HHM procedure with the intention of removing a fibroadenoma (fibroadenectomy). All patients gave written consent to the invasive procedure after being fully informed about possible risks and complications, e.g. bleeding, infection and injury to the skin. Data acquisition was retrospective using patient files. Follow-up breast ultrasound examinations of 132 women at an average follow-up interval of 9 months were considered.

Breast ultrasound was performed using a Voluson 730 Expert manufactured by GE. In each case the volume of the lesion was calculated using the ultrasound measurements reported. The vacuum-assisted biopsies were performed using the Mammotome® HH and EX systems (Ethicon Endosurgery, Inc. Cincinnati, OH 45242-2839 USA). Both systems have the same following components: control module, transport cart, holster, needle with tube system, foot switch and system software V 5.0 (product code SCMSW5). The Mammotome® devices were operated using the modes “positioning”, “tissue biopsy” and “empty needle”, which can be activated on the procedure monitor.

Ultrasound examination and biopsy procedure

For the biopsy procedure patients were positioned in a comfortable supine position keeping their ipsilateral arm held up behind their head. Lesions were measured using the ultrasound probe and lesion volume calculated. Local anaesthesia (scandicain 1%) was applied after careful disinfection of the area. The breast was draped with sterile towels while the local anaesthetic took effect. A 4 mm stab incision of the skin was then made through which the Mammotome® device needle was inserted. The needle was placed below the focal lesion under ultrasound guidance. Negative pressure was then used to aspirate the breast tissue into the biopsy chamber. A high-speed rotary knife was then pushed forward to cut the aspirated tissue off the needle in a longitudinal direction. The tissue sample could be automatically advanced to the withdrawal chamber where it was removed using forceps. The cylindrical tissue samples measured approx. 15 mm in length and 3–5 mm in diameter depending on needle size (8 or 11 gauge). This procedure could be repeated as often as necessary until the lesion was no longer detectable on ultrasound. Once the biopsy was complete the skin incision was closed using a single button suture. All patients then had a compression bandage applied for the following 24 hours.

Patient questionnaire

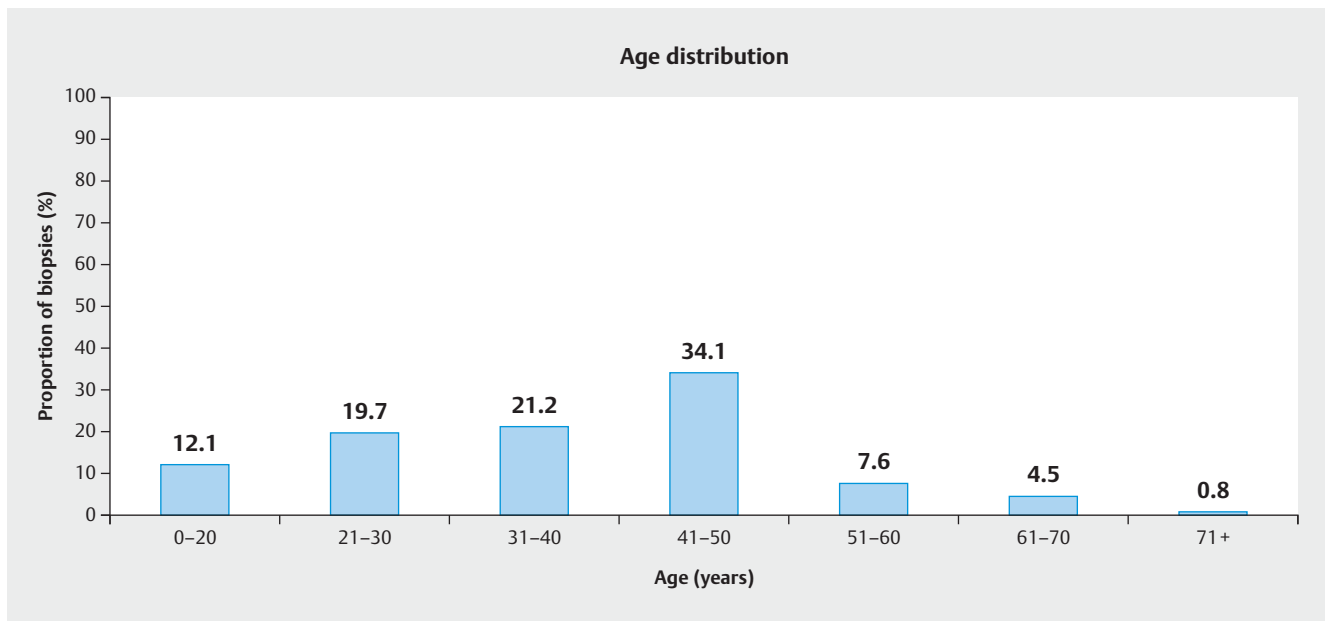
In order to assess the burden of the procedure for women prospectively, 30 patients were given a questionnaire before biopsy and asked to complete it independently after the procedure and bring it to their next follow-up appointment. Analysis was conducted anonymously to avoid possible distorting of data.

The following questions were asked:

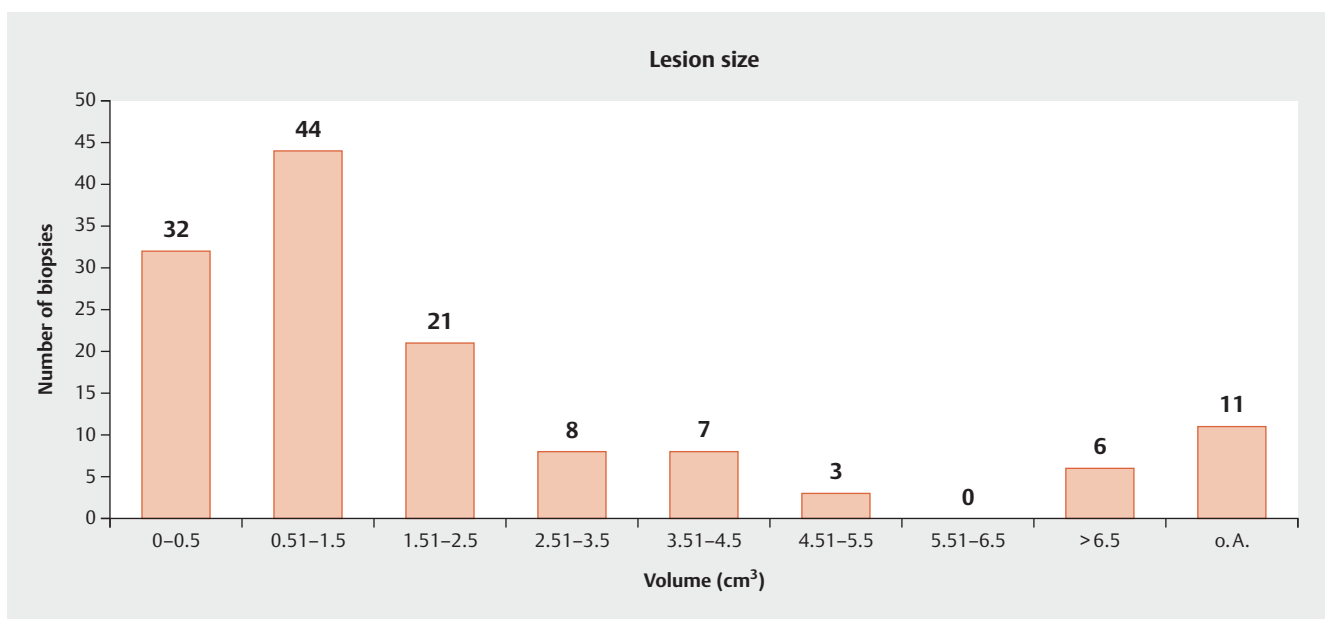
- “How severe was your pain during the biopsy?” (on a scale where 0 = no pain to 10 = unbearable)
- “How severe was your pain the day after the biopsy?” (scale from 0 = no pain to 10 = unbearable)
- “How annoying/uncomfortable did you find the compression bandage following the biopsy?” (not at all, a little, moderately, very, extremely)
- “Did a haematoma develop after the biopsy?”
- “Were there any other complications?”
- “How satisfied are you with the biopsy method you underwent?” (on a scale of 1 = very to 6 = not satisfied)
- “If it were necessary, would you agree to another vacuum-assisted biopsy?”

Statistical analysis

Data analysis was performed using the following statistical tests: the Student’s t-test for nondependent, normally distributed, random variables with expected value μ and standard deviation σ ; the fourfold χ^2 -test for distribution characteristics; the Fischer test for statistical analysis of contingency tables with expected values less than 5.



► **Fig. 1** Age distribution of patients at time of biopsy.



► **Fig. 2** Distribution of biopsies according to ultrasound determined lesion size.

Results

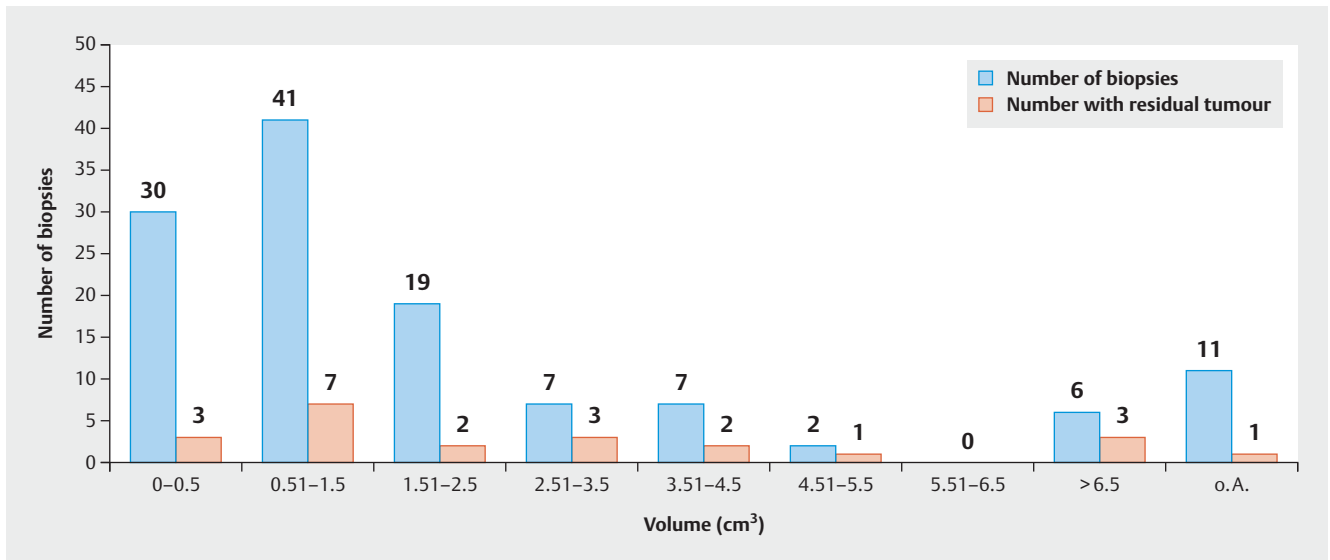
Patient characteristics

The average age of the 132 patients was 37.7 years with a standard deviation of 12.7 years (► **Fig. 1**).

In the majority of cases the lesion volume was 0.51–1.5 cm³. Data on lesion size were not available for 11 biopsies (► **Fig. 2**).

Timing of repeat ultrasound

Follow-up ultrasound was performed at an average of 259.1 days after the procedure; 26.5% were performed within 7 days, 9.1% between 8 and 30 days, 35.6% between one month and one year and 20.5% more than a year after the procedure. The exact timing of repeat ultrasound could not be determined for 2.3% of patients. In 76% of patients no residual tumour was demonstrated at follow-up ultrasound; in 17% of patients residual tumour was



► **Fig. 3** Number of procedures with residual tumour on ultrasound relative to total number of procedures according to size on initial ultrasound in cm³.

suspected. 7% of cases could not be reliably assessed for residual tumour due to either scarring or secondary haemorrhage.

Follow-up ultrasound performed within a week of biopsy showed complete fibroadenoma excision in 74.3% of cases. 17.1% had residual findings and 8.6% of cases could not be reliably assessed due to the presence of haematoma.

Among patients who were followed up between 8 days and 1 month after the procedure none had residual findings. Among those with follow-up between one month and one year after the procedure 27.7% had suspected residual tumour, 63.8% had none and 8.5% could not be reliably assessed because of scar tissue. In patients with follow-up examination after a year ultrasound showed complete fibroadenoma excision in 92.6%. 3.7% had residual tumour and a further 3.7% could not be reliably assessed.

Tumour size and residual ultrasound findings

Follow-up ultrasound findings after vacuum-assisted biopsy correlated with original tumour size. The larger the lesion initially, the greater the risk of residual tumour following the procedure. Complete excision was achieved in 86.7% of lesions smaller than 2.51 cm³ and residual tumour was significantly more likely for lesions larger than 2.51 cm³ ($p < 0.05$).

► **Fig. 3** shows the number of procedures and number of cases with residual tumour on ultrasound with respect to initial lesion size. For fibroadenomas smaller than 2.51 cm³ complete ultrasound-confirmed excision was achieved in 97 cases and 12 cases had suspected residual tumour. Despite low case numbers with larger lesions there was a trend towards an increased risk of incomplete excision for bigger tumours.

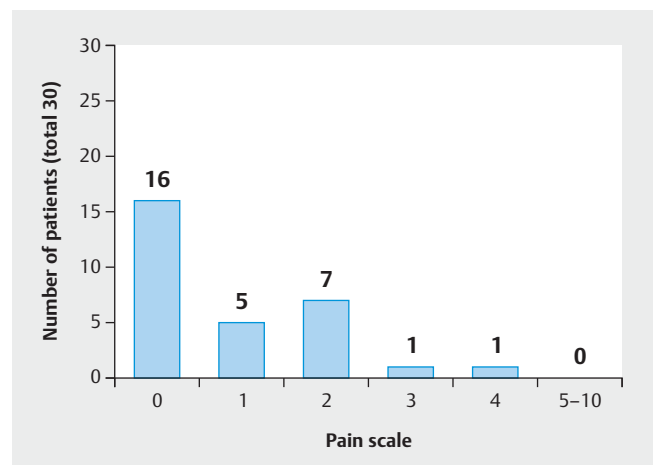
Larger tissue volumes could be obtained more quickly with 8 gauge compared to 11 gauge needles. There was however no significant association between complete excision and needle size.

Potential complications such as a need for hospitalisation, operative revision or infections requiring treatment did not occur.

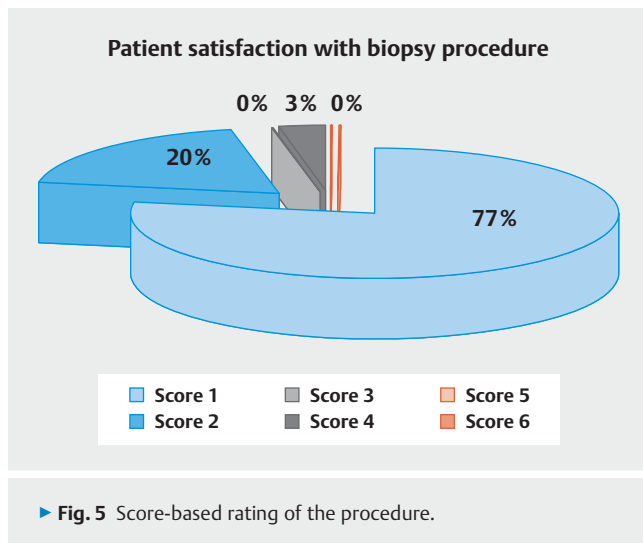
The procedure caused mild pain at most (► **Fig. 4**). The majority of women regarded the compression bandage (applied after the procedure until the following morning) as not very annoying. A good third of patients found it somewhat more problematic/uncomfortable.

90% of women reported developing a diffuse postinterventional haematoma (27 of 30 patients). 45% had no hardening of the breast after vacuum-assisted biopsy; the rest palpated a post-interventional lump between the size of a cherry and an orange.

All patients interviewed stated they would undergo this method of biopsy again if necessary, suggesting a high level of patient satisfaction and acceptance of the procedure (► **Fig. 5**).



► **Fig. 4** Patient perception of pain during biopsy.



► Fig. 5 Score-based rating of the procedure.

Discussion

The vacuum-assisted aspiration biopsy is an established minimally invasive biopsy method for the investigation of breast masses [6, 8, 13, 15]. The main advantage of this method is a reduced number of adverse effects compared to open excision biopsy. Risks of an open surgical intervention include the potential complications of general anaesthesia, greater blood loss and more scarring due to a larger wound area.

Compared to other minimally invasive breast biopsy methods such as the high-speed punch biopsy, vacuum-assisted biopsy allows the removal of greater tissue volumes, which is advantageous when complete excision is indicated.

This study was a retrospective analysis of the therapeutic applicability of ultrasound-guided vacuum-assisted biopsy for benign lesions of the female breast focussing specifically on the extent to which the HHM procedure achieves complete lesion excision as assessed by follow-up ultrasound. With ultrasound as the final measure it was shown that complete fibroadenomectomy was achieved in 76% of biopsy procedures.

Initial tumour size is a decisive criterion for postinterventional residual ultrasound findings. Fibroadenomas smaller than 2.5 cm³ could be completely removed in 87.6% of cases ($p < 0.05$). 37.5% of lesions larger than 2.5 cm³ were associated with residual findings. It is possible that lesions larger than 2.5 cm³ can not be completely removed reliably enough by vacuum-assisted biopsy. These results are in agreement with published literature. In a current (2012) consensus recommendation on the use and indications of ultrasound-guided vacuum-assisted aspiration biopsy the following conclusions are drawn: Ultrasound-guided vacuum-assisted biopsy is a suitable method for the complete excision of benign, symptomatic breast lesions and represents an alternative to open excision [9]. Only in exceptional cases should the lesion measure over 2 cm in diameter. For this tumour size rates of ultrasound-confirmed complete excision vary between 95 and 100% [8, 11, 12, 14, 18–20, 22, 23]. The technique is recommended by some for removal of benign phyllodes tumours [16]. The learning

curve is steep [17]. A recently published metaanalysis included studies comparing vacuum-assisted biopsy with open biopsy for the investigation of benign tumours [7]. 15 studies were analysed including a total of 5256 patients. No differences in tumour size, postoperative haematoma, ecchymosis, ecchymoma or residual tumour were found between HHM and open biopsy. The HHM procedure was advantageous with respect to size of skin incision, intraoperative blood loss, operation time, healing time, scar size, wound infection and cosmetic breast deformity. The authors conclude that the HHM procedure is the ideal method for removing benign breast tumours. In agreement with our results Yom et al. found that residual benign tumour was more seldom the later follow-up ultrasound was performed: when follow-up was within 2 years of the procedure residual tumour was found in 10% of cases and scar tissue in 36%. Beyond 2 years these figures were only 6.5 and 15.8% respectively [23]. The early follow-up in our study collective possibly explains the relatively high rate of suspected residual tumour.

Ultrasound-guided vacuum-assisted biopsy is almost painless.

Vacuum-assisted biopsy is a safe method of biopsy associated with few complications and only mild pain during and after the procedure. The low degree of associated pain has been confirmed by other studies. Despite its thicker needle the procedure does not cause more discomfort than high-speed punch biopsy [21]. Haematoma formation is the most common complication. 27 out of 30 patients reported haematoma development though the majority were not of therapeutic consequence [7, 10, 13, 14]. In our survey all patients stated they would undergo the biopsy again if necessary. High patient satisfaction with the procedure has also been reported by others [22].

Thus the vacuum-assisted breast biopsy is an appropriate, effective and accepted method for the excision of benign breast lesions.

Conflict of Interest

The authors declare no conflict of interest.

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